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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,424	04/20/2001	David L. Brown	3364/1 (PHA 4176)	1761

7590

06/17/2003

Pharmacia Corporation
Corporate Patent Department
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EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 06/17/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,424

Applicant(s)

BROWN ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-113 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,17-30,33,34,39,42-91,93,95-98,100 and 102-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-16, 31-32, 35-38, 40, 41, 92, 94, 99, 101, 105-113 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Detailed Action

(old rejection)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-8, 11-16, 31-32, 35-38, 40, 41, 92, 94, 99, 101, 105-113 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the radicals A equal to all 5 or 6 membered heterocyclic rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the

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level of predictability in the art 6) the amount of direction provided by the inventor

7) the existence of working examples, and 8) the quantity of experimentation

needed to make or use the invention based on the content of the disclosure. In

re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims 1 encompasses a much wider Markush grouping of radicals than those tested. In terms of factor 3 and 5, the state of the art and the level of predictability in the art cannot be predicted with any certainty beyond what specific test compounds /compositions and/or additional therapeutic agents should be used and are likely to provide productive results beyond those therapeutic compounds/compositions and/or additional therapeutic agents taught in the specification.

In terms of factors 4 and 6, the inventor provides no guidance beyond the therapeutic compound/compositions and/or therapeutic agents as taught in the specification as previously mentioned. As a result one of ordinary skill in the art could not predict what other types of therapeutic compounds/compositions and/or additional therapeutic agents, other than those taught in the specification; and with regards to the 7th and 8th wands factor, while the existence of working examples are limited to the aforementioned compounds/compositions as taught in the specification, an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on the diseases claimed.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above

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factors into consideration, it is not seen where the instant claim is enabled by the instant application.

There is no reasonable assurance that the different heterocyclic ring systems would have the alleged properties. See *in re Fouche*, 169 USPQ 429 (CCPA 1971).

There is insufficient exemplification to show that all of the ring systems would be attained synthetically without description. There is no indication that steric hindrance has been avoided.

Response to Applicant's Remarks

112, first paragraph enablement rejection

The applicant's assert that the application is enabled because they assert that the mere fact that some experimentation is required does not mean that the application is not enabled. The applicant's also assert that they are not required to show a specific example for every possible embodiment of the claimed subject matter. However, an undue amount of experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor.

The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention undue or unreasonable. That standard is still the one to be applied. In *re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In *re Buchner*, 929 F.2d 660,

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661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). The question of what constitutes undue experimentation was considered by the Federal Circuit in **In re Wands** [49] where the Court noted a prior decision of the PTO Board of Appeals [50], which had listed factors to be considered, and then applied them to the case before it. The factors to be considered were:

- (1) the quantity of experimentation necessary;
- (2) the amount of direction or guidance provided;
- (3) the presence or absence of working examples;
- (4) the nature of the invention;
- (5) the state of the prior art;
- (6) the relative skill of those in the art;
- (7) the predictability or unpredictability of the art; and
- (8) the breadth of the claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The applicant does not do this with regard to the synthesis and use of compounds, where A can equal all 5 or 6 membered heterocyclic rings. Additionally, the applicant does not test the whole breadth of compounds encompassing all of the moieties that these particular radicals can be. There is no reasonable correlation between the narrow disclosure in applicant's and the broad scope of protection sought in the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson



June 16, 2003



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600